

Guidance for Industry and Tobacco Retailers

Enforcement Policy for Certain (Provisional) Tobacco Products that FDA Finds Not Substantially Equivalent

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments regarding this draft guidance may be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Electronic comments may be submitted to <http://www.regulations.gov>. Alternatively, submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD, 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft guidance, contact the Center for Tobacco Products at (Tel) 1-877-CTP-1373 (1-877-287-1373) Monday-Friday, 9 a.m. – 4 p.m. EDT.

Additional copies are available online at

<http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm>.

You may send an e-mail request to SmallBiz.Tobacco@fda.hhs.gov to receive an electronic copy of this guidance. You may send a request for hard copies to U.S. Food and Drug Administration, Center for Tobacco Products, Attn: Office of Small Business Assistance, 9200 Corporate Blvd., Rockville, MD 20850.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Tobacco Products**

February 2014

Guidance for Industry and Tobacco Retailers¹

Enforcement Policy for Certain (Provisional) Tobacco Products that FDA Finds Not Substantially Equivalent

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

FDA is issuing this draft guidance to provide information on its enforcement policy to retailers regarding so called “provisional” tobacco products that become subject to not substantially equivalent orders issued under section 910(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). The “provisional” tobacco products addressed by this draft guidance are tobacco products that were first introduced or delivered for introduction into interstate commerce for commercial distribution after February 15, 2007, and prior to March 22, 2011, and for which a 905(j) (or substantial equivalence) report was submitted no later than March 22, 2011. Under the FD&C Act, tobacco products meeting these criteria were permitted to remain on the market pending FDA's review of such report. If FDA issues an order finding the product not substantially equivalent (NSE), the product is adulterated and misbranded (sections 902(6)(A) and 903(a)(6) of the FD&C Act; 21 U.S.C. 387b(6)(A), 387c(a)(6)). This means that, effective immediately upon issuance of an NSE order, it is a prohibited act to sell or distribute the product in interstate commerce, to import such products into the United States, or to receive from interstate commerce and sell or offer to sell or otherwise deliver products. In addition, a tobacco product that is the subject of an NSE order is subject to seizure at any time.

Because the FD&C Act permitted this specific group of products to remain on the market pending FDA's review of the report, there will very likely be products at retail locations within the United States when FDA issues an order finding a tobacco product NSE. FDA does not intend to take enforcement action for at least 30 calendar days from the date the NSE order

¹ This draft guidance was prepared by the Office of Compliance and Enforcement and Office of Regulations in the Center for Tobacco Products at FDA.

Contains Nonbinding Recommendations

Draft – Not for Implementation

issues for those products that are in the retailer's current inventory at a specific retail location on the date FDA issues the NSE order. This policy extends only to tobacco products that are already in a retail store that offers the products for sale directly to consumers. FDA encourages retailers to contact their supplier or manufacturer to discuss possible options for the misbranded and adulterated product that they may have in their current inventory.

FDA's guidance documents, including this draft guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.